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2394 Route 130 • Dayton, New Jersey 08810 • www.productsafetylabs.com
732-254-9200 • 800-425-0002 • FAX-732-254-6736

Thursday, November 01, 2001

Philip Wolfson
PHYTOS INC.
6 Crest Rd
San Anselmo, CA 94960

Dear Dr. Wolfson:

Enclosed please find the following FINAL REPORT for Gold Root Extract:

Study #11325 - P203 Acute Oral Toxicity Study in Rats

Invoice will be sent under separate cover.

Thank you for your confidence in Product Safety Labs. Please contact Daniel J. Merkel, our Study Director, for comments and/or questions.

Sincerely,

Tammy Paleopanidis

Enc.

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ACUTE ORAL TOXICITY STUDY IN RATS - LIMIT TEST

TEST METHOD NO.:	P203
STUDY NUMBER:	11325
SPONSOR:	PHYTOS, INC. 6 Crest Road, San Anselmo, California 94960
TEST SUBSTANCE IDENTIFICATION:	Gold Root Extract
TEST SUBSTANCE DESCRIPTION:	Yellow powder
DATE RECEIVED:	September 19, 2001
PSL REFERENCE NO.:	010919-8D
DATES OF TEST:	September 26 - October 10, 2001
NOTEBOOK NO.:	01-47: pages 208-213

1. PURPOSE

To provide information on health hazards likely to arise from a short-term exposure to Gold Root Extract by the oral route.

2. PROCEDURE

A group of Sprague-Dawley derived, albino rats was received from Ace Animals, Inc., Boyertown, PA. The animals were singly housed in suspended stainless steel caging with mesh floors. Litter paper was placed beneath the cages and was changed at least three times per week. The animal room was temperature controlled and had a 12-hour light/dark cycle. The animals were fed Purina Rodent Chow #5012 and filtered tap water was supplied *ad libitum* by an automatic watering system.

Following acclimation to the laboratory, a group of animals was fasted for approximately 19 hours by removing feed from their cages. After the fasting period, ten rats (five male and five female) were selected for test based on health and initial bodyweights. Individual doses were calculated based on these bodyweights, taking into account the specific gravity (determined by PSL) of the test substance. The test substance was administered as a 45% w/w suspension in distilled water. Each animal received 5,000 mg/kg of the test substance by intubation using a stainless steel ball-tipped gavage needle attached to an appropriate syringe. After administration, each animal was returned to its designated cage. Feed was replaced approximately 4 hours after dosing.

The animals were observed for mortality, signs of gross toxicity and behavioral changes at approximately one hour post dosing and at least once daily for 14 days. Bodyweights were recorded prior to initiation and at termination. All animals were euthanized by CO_2 inhalation at termination.

3. RESULTS

Individual bodyweights and doses are presented in Table 1. Cage-side observations are presented in Table 2.

Apart from one female that exhibited an abnormal gait 2 hours after administration, all animals survived, gained weight and appeared active and healthy. There were no other signs of gross toxicity, adverse pharmacologic effects or abnormal behavior.

4. CONCLUSION

Under the conditions of this study, the single dose acute oral LD_{50} of Gold Root Extract is greater than 5,000 mg/kg of bodyweight in male and female rats.

SIGNATURES

Gold Root Extract

We the undersigned declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.

Daniel J. Merkel, B.S.
Study Director

October 31, 2001
Date

Frank Fielder, B.S.
Quality Assurance Supervisor

October 31, 2001
Date

TABLE 1: INDIVIDUAL BODYWEIGHTS, DOSES AND MORTALITY

Animal No.	Sex	Bodyweight (g)		Dose[1]
		Initial	Day 14	ml
6349	M	233	361	2.3
6350	M	232	347	2.3
6351	M	239	355	2.3
6352	M	252	369	2.5
6353	M	246	374	2.4
6354	F	175	236	1.7
6355	F	171	239	1.7
6356	F	179	244	1.7
6357	F	178	250	1.7
6358	F	186	249	1.8

[1] Administered as a 45% w/w suspension in distilled water. Specific Gravity - 1.139 g/ml.

TABLE 2: INDIVIDUAL CAGE-SIDE OBSERVATIONS

Animal Number	Findings	Day of Occurrence
MALES		
6349 - 6353	Active and healthy	0-14
FEMALES		
6354 - 6357	Active and healthy	0-14
6358	Abnormal gait Active and healthy	0 (2 hrs) 0 (1 hr), 0(3 hrs)-14

TABLE 3: INDIVIDUAL NECROPSY OBSERVATIONS

Animal Number	Tissue	Findings
MALES		
6349-6353	All tissues/organs	No gross abnormalities
FEMALES		
6354-6358	All tissues/organs	No gross abnormalities

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January 28, 2002

Dr. Philip Wolfson
PHYTOS INC.
6 Crest Rd
San Anselmo, CA 94960

Dear Dr. Wolfson:

At the request of Dr. Ted Farber, I am writing to provide you with a preliminary description of the results of the 28 day study on Gold Root Extract. The study was conducted with three test groups (low, mid and high dose level) and 1 negative control group. The test compound was incorporated into the diets of the animals assigned to the test groups at levels of 130, 1,300 and 13,000 ppm.

As you know, the "in-life" portion of the study ended last week. The amount of information we have at this time is limited. What I can tell you is that animals from all test groups survived, gained weight and appeared active and healthy during the 28 day study. Gross necropsy findings at terminal sacrifice were unremarkable. Evaluation of the following parameters are still pending; food consumption, bodyweight gain, organ to bodyweight ratios, clinical chemistry, hematology and histopathology. Once we have compiled this data, we will be provide you with a final report describing our findings in more detail.

Please feel free to contact me if you have any questions or need additional information.

Sincerely,
PRODUCT SAFETY LABS

Gary Wnorowski
Laboratory Director